TCT-844

Active Versus Passive Anchoring Vascular Closure Devices: A Safety and Efficacy Comparative Analysis

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Background: We evaluate the prevalence of complications and failure rates between the most commonly used "active" anchoring vascular closure device (VCD), AngioSeal™ and the "passive" anchoring VCD, Mynx,™ in all-comers undergoing percutaneous coronary intervention (PCI).
Methods: A total of 4,074 patients between 2008-2014, representing an era when both devices were available, were included. 32% were acute coronary syndromes (37% STEMI). VCD choice was at the operator's discretion and included AngioSeal (n=2910) or Mynx (1,164). Cardiogenic shock or patients receiving intra-aortic balloon pumps were excluded. Safety was assessed by vascular complications defined as either vascular injury (perforation, dissection, acute limb ischemia, arteriovenous fistula, pseudoaneurysm with thrombin injection, or surgical repair) or access-site bleed (hemoglobin drop >3 g/dL requiring transfusion, retroperitoneal bleed, or hematoma >5cm, or the composite of both. Efficacy was evaluated by device failure defined as inability to achieve immediate hemostasis, or additional hemostatic mechanisms require. Outcomes at 30-days were evaluated.
Results: Groups (AngioSeal vs. Mynx) were fairly balanced with regards to bleeding risk factors of gender (male, 65% vs. 66%), body mass index (30±6 vs. 30±7), heart failure class III/IV (5% vs. 6%), chronic kidney disease (15% vs. 17%), use of glycoprotein IIb/IIIa inhibitor (5% vs. 4%) or bivalirudin (86% vs. 88%), all p >0.5. The AngioSeal group was slightly younger (64±12 vs. 65±12, p < 0.001) with less peripheral arterial disease (11.3% vs. 13.9%, p =0.03), and increased 7F sheath use compared with Mynx (59% vs. 22%, p < 0.001). Safety and efficacy outcomes were similar between groups (table).
Conclusions: AngioSeal and Mynx appear to be equally safe and efficacious VCDs following PCI. The passive anchoring system may prove desirable as no intra-arterial anchor remains upon device removal.

	Outcomes		
	AngioSeal (n=2,910)	Mynx (n=1,164)	p value
Safety			
Vascular injury	0.30%	0.80%	0.09
Access-site bleed	1.90%	1.40%	0.8
Composite safety	2.30%	1.50%	0.6
Efficacy			
Device failure	7.50%	8.70%	0.4

TCT-845

Femoral Approach with Systematic Use of FemoSeal™ Closure Device Compared to Radial Approach in Primary Angioplasty: a Propensity-matched Comparison

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Background: Radial approach (RA) has been shown to reduce access-related bleedings as compared to femoral approach (FA). However, although the risk of femoral bleeding can be reduced with the adoption of vascular closure devices (VCD), there are few data about the comparison of RA and FA with VCD, particularly in patients at high risk of bleeding such as those undergoing primary percutaneous coronary intervention (pPCI). The FemoSeal™ (St.Jude Medical,MN,USA) is a sandwich type, fully resorbable VCD that has been associated with a low rate of access-site bleeding and vascular complications. Aim of this study was to compare the incidence of bleedings, defined according to the Thrombolysis in Myocardial Infarction (TIMI) criteria, and of major adverse cardiac and cerebrovascular events (MACCE) in a population of patients undergoing primary angioplasty through RA or FA with systematic closure by FemoSeal™.
Methods: We included in this retrospective registry 777 patients who underwent pPCI at two high-volume Centers from years 2010 to 2013. Exclusion criteria were the implantation of intra-aortic balloon pump and the achievement of femoral hemostasis by other means than the FemoSeal™. The study population was divided in RA patients, enrolled in Center A (Group 1, n=511) and FA patients, enrolled in Center B (Group 2, n=266). We performed multivariate analysis and propensity-score matching in order to adjust for clinical and procedural confounders.
Results: Main results of the study are provided in the Table. At multivariate analysis, the following predictors of bleeding were identified: FA (OR 3.2, 95% C.I. 1.3-7.5), use of Gp IIb/IIIa blockers (OR 3.6, 95% C.I. 1.5-8.7) and heart rate at presentation (OR 1.04, 95% C.I. 1.02-1.07).
Conclusions: In primary PCI the rate of TIMI major bleedings was higher in FA with closure by FemoSeal™ as compared to RA, whereas the rates of minor bleedings and of MACCE were similar.

	Group 1	Group 2	p
General population (n)	511	266	
TIMI major (%)	0.2	2.3	<0.01
TIMI minor (%)	2.0	3.4	0.22
MACCE (%)	3.5	3.4	0.9
Propensity-matched population (n)	229	229	
TIMI major (%)	0	2.6	<0.05
TIMI minor (%)	1.3	3.9	0.79
MACCE (%)	4.4	2.6	0.44

TCT-846

Radial-to-femoral access crossover is not associated with adverse outcomes in the setting of primary percutaneous coronary intervention

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Background: We aimed to describe the impact of the vascular access used when patients are treated with primary percutaneous coronary intervention (PPCI) and to assess whether this translates into differences in angiographic outcomes.
Methods: ST-elevation myocardial infarction (STEMI) patients undergoing PPCI were divided into three groups: successful radial access (RA), successful femoral access (FA) and Crossover (failed RA with need for bailout FA) groups. Vascular access-related time (VART) was defined as the delay in PPCI that can be attributed to vascular access-related issues. Study endpoint was the final corrected TIMI frame count (CTFC). Multivariable analysis was used to identify predictors of RA failure (RAF: FA+Crossover).
Results: We included 241 patients (RA n=172, FA n=49, Crossover n=20). Mean VART was longer in Crossover (10.3 (8.8-12.4) min), relative to RA (4.1 (3.2-5.5) min) and FA (4.6 (3.4-8.4) min, p< 0.001). A similar situation was found for time-to-first-device (Crossover: 22.5 (20.3-32.0) min; RA: 15.0 (12.0-19.8) min; FA: 17.9 (13.5-22.3) min; p< 0.001) and total procedure time (Crossover: 60.3 (51.6-71.5) min; RA: 46.8 (38.1-59.7) min; FA: 52.3 (41.9-74.7) min; p< 0.001). No differences in CTFC were observed (Crossover: 26 (18-32) frames; RA: 24 (18-32) frames; FA: 25 (16-34) frames; p=0.625). Killip class IV (OR 3.628, 95% CI: 1.098-11.981, p=0.035), cardiopulmonary resuscitation prior to arrival (OR 3.572, 95% CI: 1.028-12.407, p=0.045) and glomerular filtration rate (OR 0.861, 95% CI: 0.758-0.978, p=0.021) were independent predictors of RAF.
Conclusions: In the setting of PPCI, radial-to-femoral access crossover can lead to VART delays that do not impact angiographic outcomes, in comparison with successful RA. Killip class IV, cardiopulmonary resuscitation prior to arrival and impaired renal function are independent predictors of RAF in STEMI patients undergoing PPCI.

TCT-847

Safety And Efficacy Of Angio-Seal® Vs. Exo-Seal® In Patients Undergoing Primary Percutaneous Coronary Intervention For ST-elevation Myocardial Infarction

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Background: Patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) are at high risk of femoral vascular complications (VC). In spite of the growing use of radial approach, femoral remains the most common in primary PCI. The use of femoral vascular closure devices (VCDs) has expanded in recent years despite previous controversial trials. Angio-Seal® is a collagen-based plug/anchor intravascular device and Exo-Seal® is an extravascular polyglykolacid plug. Objective: to evaluate safety and efficacy, and to compare these VCDs in primary PCI.

Methods: We included 827 consecutive patients who underwent primary PCI by femoral access in our institution between August 2009 to October 2013 with a 6 months follow-up. Primary end point was the presence of VC defined as a composite of hematoma> 6 cm, recurrent bleeding, pseudoaneurysm, arteriovenous fistula, arterial thrombosis or retroperitoneal bleeding.
Results: 404 (48.8%) patients received Angio-Seal® and 423 (51,2%) Exo-Seal®. 39 (4,7%) patients had a VC with a similar incidence of events between the 2 VCDs: 18 (4,4%) in Angio-Seal® and 21 (4,9%) in Exo-Seal® (p=0.7). Risk of VC was significantly associated with body mass index (p=0.01), sheath size (p=0.04), presence of chronic kidney disease (p=0.005) and peripheral arterial disease (p=0.03). There was no fatal complications. Most of the pseudoaneurysms were resolved with compression and/or thrombin, only 2 of them and 1 retroperitoneal bleeding required vascular surgery.
Conclusions: Although radial approach is increasing in recent years, femoral remains the most frequent in primary PCI. VC after femoral VCDs in patients undergoing primary PCI, have a low but not negligible incidence despite being implanted by interventional cardiologists experienced in femoral access. VC were significantly associated with individual (body mass index, chronic kidney disease, peripheral arterial disease) and procedure-related (sheath size) characteristics. Safety and efficacy of both (Angio-Seal® and Exo-Seal®) VCDs is similar after primary PCI.

TCT-848

Mynx™ Vascular Closure Device Achieves Reliable Closure and Hemostasis of Large Bore Percutaneous Trans-Femoral Venous Access in a Porcine Vascular Model: Acute and 30 Day Evaluation using Angiography, Ultrasound, and Histology

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Background: Vascular closure device (VCD) based venous closure has been anecdotally reported but systematic evaluation of the reparative response of the vessel wall to venous closure is lacking. The need to control groin complications, and minimize risks associated with postponed sheath removal under conditions of persistent anticoagulation, has generated interest in the role of vascular closure devices for venous access closure. We sought to characterize the vessel wall response to venous closure, both acutely and in delayed fashion at 30 days using angiography, ultrasound and histology.
Methods: Ten (10) venous 7F sheaths were deployed in the femoral veins of swine. Bilateral venous access sites were subsequently closed utilizing manual compression (control arm, n=4) or a closure device utilizing an extravascular polyethylene glycol sealant (MynxGrip Treatment arm, n=6). Acute (post-closure), 3-day and 30-day vascular ultrasound, as well as venography was used to assess outcomes. Gross pathology and histology were obtained at the 30 day endpoint for all femoral venous closure sites.Each animal was evaluated for venous thromboembolism to downstream tissues vena cava, heart, and lungs.
Results: Hemostasis was successfully achieved in all cases without access site complications. Venography and ultrasound confirmed normal ilio-femoral anatomy and flow at all study time points. Gross pathology and histopathology revealed no evidence of deep vein thrombosis, and no abnormalities were seen in the vena cava, heart or lungs. Histology (at 30 days) showed complete healing of the vein wall access site, with a small focus of chronic inflammation and fibrosis in the perivascular adventitial tissue of the access tract. There was no microscopic evidence of the sealant. The tissue tract showed mild discrete inflammation (foamy macrophages, lymphocytes, plasma cells) with micro-granulomas centered on residual red cells in both treatment and control groups.
Conclusions: This study provides novel insight into healing mechanisms following femoral vein closure and the bioresorptive role of MynxGrip™ extravascular sealant in achieving effective venous closure, while preserving long term vessel patency without thromboembolism.

TCT-849

Preclosure of vascular access site with the suture-mediated ProGlide system during transfemoral TAVI and MitraClip implantation

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Background: The ProGlide closure system is becoming popular for the percutaneous delivery of suture for closing the vascular access site of patients who have undergone structural interventional procedures using 5F to 21F sheaths. This study is intended to demonstrate the safety, effectiveness and feasibility of a suture-mediated ProGlide for access site closure after transfemoral transcatheter aortic valve implantation (TAVI) and transfemoral MitraClip.
Methods: ProGlide closure was used between 2010 and 2013 in 57 patients in our centre. The ProGlide sutures were deployed in a preclose technique before the insertion of the large caliber sheath. Achieving effective hemostasis and no further access site-related vascular or hemorrhagic complications during the whole hospital stay is considered success of the closure technique.
Results: Patients were 73+/-6.5 years old with a logistic EuroSCORE of 22.2+/-12.4. There were total of 57 patients deemed high risk as surgical candidates undergone percutaneous therapy for transfemoral TAVI with Edwards SAPIEN valves (n=31) and MitraClip procedure (n=26). The overall success rate of the ProGlide closure was 98.3%(one patient had diminished pulses distal to closure site that needed surgical intervention). The success rate remained at 100% among the patients on dual antiplatelet therapy (DAPT) or on anticoagulants. None of the patients that were examined with ultrasound demonstrated an AV fistula, aneurysm, hematoma or local thrombosis related to the ProGlide device.
Conclusions: This study demonstrated that the suture-mediated ProGlide system is a safe, simple and highly effective method to close the large arterial access site after transfemoral TAVI and large venous sites of 24Fr as needed in patients undergoing MitraClip procedure despite on platelet inhibitors or anticoagulation. Additionally, use of the ProGlide system can result in shorter procedure time, duration to achieve hemostasis and also shorter length of hospital stay.

TCT-850

Patients undergoing PCI via the femoral artery in a default radial centre have very high BARC bleeding rates and subsequent bleeding 30 day and 1 year mortality

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Background: Increasingly the trans-radial route (TR) is preferred over the trans-femoral route (TF) for PCI. However even in high volume default TR centres a small cohort of patients are required to undergo TF PCI. We examined the demographics, procedural and bleeding outcomes of patients undergoing PCI via the TF in a single high volume UK centre.
Methods: The patient demographics procedure and outcomes of 5379 patients undergoing PCI between 2009 and 2012 were examined. 559(10.4%) patients underwent PCI via the TF route reviewed for Hb drop 3g/dl or more, overt bleeding, Transfusion with in 7 days post PCI, Doppler US/ CT abdomen.
Results: 559(10.4%) patients underwent PCI via the TF route and these patients were more often female, older, lower body weight, shocked and undergoing complex procedures than patients in the TR cohort. In the TF group 79 patients (16.4%) experienced bleeding with 1 each BARC Type 5a and 5b bleed each, 3 BARC Type 3b bleeds, 17 Type 3a bleeds and 57 Type 2 bleeds. Within the TF cohort patients with bleeding when compared to TF patients without bleeding were less likely to have stable angina (13.9% vs. 38.5%, p< 0.0001), more likely to be undergoing primary PCI (30.4% vs. 9.4%, p< 0.0001), present with cardiogenic shock (24.1% vs. 3.5%, p< 0.0001), have sheath sizes greater than 6F used and have a lower BMI (26.0 vs. 32.3 in females and 27.2 vs. 30.0 in males). Mortality at 30 days (15.2% vs. 1.9%, p < 0.0001) and 1 year (25.3% vs. 5.2%, p< 0.0001) was significantly higher in the bleeding group. Major bleeding was an independent predictor of 30 day and 1year mortality.
Conclusions: In a high volume default TR centre the incidence of BARC-defined bleeding was extremely high in TF PCI patients with excess mortality at 30 days and 1 year. Therefore TF PCI cases undertaken in a default TR centre cases require meticulous peri-procedural and post-procedural care to minimise complications.